

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Keith, et al.

Confirmation No.: 2818

Patent No.: 7,501,118 B2

Group Art Unit: 1647

Serial No.: 10/670,184

Filed: September 24, 2003

Examiner: Saoud, Christine J.

For: HUMAN GENE RELATING TO RESPIRATORY DISEASES AND OBESITY

PETITION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

UNDER 37 C.F.R. § 1.705(d)

Mail Stop **Petitions**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby petition for reconsideration of the Determination of Patent Term Adjustment under 35 U.S.C. §154(b) for U.S. Patent No. 7,501,118 B2.

In accordance with to 37 C.F.R. §1.705(d), applicants submit herewith 1) the fee set forth in 37 C.F.R. §1.18(e) and 2) a statement of the facts involved.

STATEMENT OF FACTS

On September 24, 2003, the application which issued as U.S. Patent No. 7,501,118 B2 was filed in the U.S. Patent & Trademark Office (USPTO), thus qualifying for Patent Term Adjustment (PTA) under 35 U.S.C. §154. The instant application is not currently subject to a terminal disclaimer.

On March 10, 2009, the USPTO issued the above-referenced patent indicating that the Patent Term Adjustment Under 35 U.S.C. 154(b) was **683** days (see Exhibit 1).

We have reviewed the prosecution history of the above-referenced application and confirm that the term calculation by the USPTO is 683 days according to **35 U.S.C. § 154(b)(1)(B)** (i.e., 898 days delayed by USPTO in issuing the patent beyond 3 years – 215 days delayed by applicants) (see Exhibit 2). However, this term adjustment fails to consider the delays by the USPTO during prosecution of the application according to **35 U.S.C. § 154(b)(1)(A)**.

In relevant part, 35 U.S.C. § 154 states (emphasis added):

(b)ADJUSTMENT OF PATENT TERM.—

(1)PATENT TERM GUARANTEES.—

(A)GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.—

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

(i)provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title **not later than 14 months after**—

(l)the date on which an application was filed under section 111(a) of this title; or

* * *

(B)GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the **failure of the United States Patent and Trademark Office to issue a patent within**

3 years after the actual filing date of the application in the United States, not including—

* * *

Applicants submit that the correct patent term calculation under 35 U.S.C. § 154 for the above-referenced patent is **1203 days**. Applicants' calculation of PTA properly includes:

1. 520 days of delay by the USPTO in issuing the first Office Action after 14 months from the filing date (from November 24, 2004 to April 28, 2006);
2. 898 days of delay by the USPTO in issuing the patent beyond 3-years-from-filing-date (from September 24, 2006 to March 10, 2009); and
3. An adjustment of 215 days of delay by the applicant during prosecution (three responses submitted with petitions for extensions of time).

Exhibit 2 (submitted herewith) is a printout from the USPTO PAIR website which shows the USPTO's calculations of the number of days of delay by the USPTO and applicants for the subject patent. These calculations are in accordance with the applicants' determination above. Therefore, based on the proper interpretation of 35 U.S.C. § 154, applicants are entitled to **1203 days** of PTA (520 days + 898 days – 215 days).

Applicant's view is supported by recent case law interpreting 35 U.S.C. § 154. Wyeth, et al. v. Jon W. Dudas, 580 F. Supp. 2d. 138 (D.D.C. 2008). In Wyeth the federal District Court for the District of Columbia granted summary judgment in favor of Wyeth, determining that the U.S. Patent and Trademark Office had misconstrued 35 U.S.C. § 154(b)(2)(A). As a result, the Office had denied Wyeth a portion of patent term to which it was entitled under the law. Wyeth held, and the court agreed, that the proper PTA includes USPTO delays before the 3-years-from-filing date plus all delays between the 3-years-from-filing date and the issue date, less applicant delays; and, that this would not constitute impermissible "double-counting" of delay periods.

Applicants respectfully assert that the USPTO's Determination of PTA has been improperly calculated and respectfully request adjustment of the 683 days of PTA to **1203 days**.

CONCLUSION

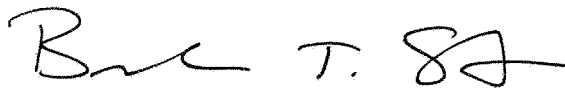
In considering the evidence as detailed in Image File Wrapper and Transaction History of the Patent Application Information Retrieval (PAIR) system, Applicants respectfully request reconsideration of the Patent Term Adjustment and request that the patent which issues from the instant application be accorded the correct Patent Term Adjustment.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **504827**, Order No. 1004438.012US.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **504827**, Order No. 1004438.012US.

Respectfully submitted,
Locke Lord Bissell & Liddell LLP



Dated: May 8, 2009

By: _____
Brandon T. Schurter
Registration No. 59,668

Correspondence Address:
CUSTOMER NO: **85775**

(212) 415-8600
(212) 303-2754

Telephone
Facsimile

Exhibit 1

Patent No.:	7,501,118 B2
Application Serial No.:	10/670,184
Applicant(s):	Keith, et al.
Group Art Unit:	1647
Filed:	September 24, 2003
Examiner:	Saoud, Christine J.
For:	HUMAN GENE RELATING TO RESPIRATORY DISEASES AND OBESITY



US007501118B2

(12) **United States Patent**
Keith et al.

(10) **Patent No.:** **US 7,501,118 B2**
(45) **Date of Patent:** **Mar. 10, 2009**

(54) **HUMAN GENE RELATING TO
RESPIRATORY DISEASES AND OBESITY**

FOREIGN PATENT DOCUMENTS

(75) Inventors: **Tim Keith**, Bedford, MA (US); **Randall Little**, Newtonville, MA (US); **Paul Van Eerdewegh**, Weston, MA (US); **Josée Dupuis**, Newton, MA (US); **Richard Del Mastro**, Norfolk, MA (US); **Jason Simon**, Westfield, NJ (US); **Kristina Allen**, Hopkinton, MA (US); **Sunil Pandit**, Gaithersburg, MD (US)

EP	1134286	9/2001
WO	WO 97/09420	3/1997
WO	WO 97/31109	8/1997
WO	WO 99/03878	1/1999
WO	WO 01/09293	2/2001
WO	WO 01/78894	10/2001
WO	WO 01/83782	11/2001
WO	WO 02/24927	3/2002
WO	WO 02/38744	5/2002
WO	WO 02/83077	10/2002

(73) Assignee: **Oscient Pharmaceuticals Corporation**, Waltham, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 683 days.

(21) Appl. No.: **10/670,184**

(22) Filed: **Sep. 24, 2003**
(Under 37 CFR 1.47)

(65) **Prior Publication Data**
US 2004/0077011 A1 Apr. 22, 2004

Related U.S. Application Data

(62) Division of application No. 09/548,797, filed on Apr. 13, 2000, now Pat. No. 6,683,165.
(60) Provisional application No. 60/129,391, filed on Apr. 13, 1999, provisional application No. 60/146,336, filed on Jul. 30, 1999.

(51) **Int. Cl.**
A61K 39/395 (2006.01)
A61K 39/44 (2006.01)
C07K 16/18 (2006.01)
C07K 17/00 (2006.01)

(52) **U.S. Cl.** **424/130.1**; 530/387.1; 530/387.9;
530/388.1; 530/388.24; 530/389.2; 530/391.1

(58) **Field of Classification Search** None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,011,912	A *	4/1991	Hopp et al.	530/387.9
5,552,526	A	9/1996	Nakamura et al.	
6,420,154	B1	7/2002	Sheppard et al.	
2003/0027275	A1 *	2/2003	Baker et al.	435/69.1

OTHER PUBLICATIONS

GenBank Accession No. AA44255, Jun. 4, 1997, Hiller et al.
GenBank Accession No. AL117415, Sep. 15, 1999, Blum et al.
GenBank Accession No. AC017113, Dec. 14, 1999, Waterston.
GenBank Accession No. AC055771, Apr. 20, 2000, Birren et al.
Eerdewegh et al., 2002, *Nature*, 418:426-430.
Alfandari et al., 1997, *Devel. Biol.*, 182:314-330.
Collins et al., 2000, *Genetics and Mol. Biol.*, 23:1-10.
D.R. Dunbar et al., 1997, "In situ hybridization mapping of genomic clones for five human respiratory chain complex 1 genes" *Cytogenet. Cell Genet.* 78:21-24.
A.V. Lemberas et al., 1997, "Identification of an obesity quantitative trait locus on mouse chromosome 2 and evidence of linkage to body fat and insulin on the human homologous region 20q" *J. Clin. Invest.* 100:1240-1247.
M. Hattori, et al., "Homo sapiens 206,647 genomic DNA of 20p," GenBank Accession No. AP002898, Submitted Oct. 22, 2000.
GenBank Accession No. NM023038, Feb. 10, 2001, Wang, et al.
GenBank Accession No. NM033274, Sep. 6, 2001, Fritsche, et al.
SNP Accession No. RS1422795, Dec. 1998.
Howard, et al., 2002, *American Journal of Human Genetics*, 71:488.
Van Eerdewegh, et al., 2002, *American Journal of Human Genetics*, 71:191.
Supplementary Partial European Search Report for the related European national phase application No. 02795518.6 of the PCT Application No. PCT/US02/32700, actual completion of the European search date Apr. 26, 2007; date of mailing May 21, 2007.

* cited by examiner

Primary Examiner—Christine J Saoud

(74) *Attorney, Agent, or Firm*—Morgan & Finnegan, L.L.P.

(57) **ABSTRACT**

This invention relates to isolated nucleic acids comprising genes of human chromosome 20p13-p12 and the proteins encoded by these genes. Expression vectors and host cells containing such genes or fragments thereof, as well as antibodies to the proteins encoded by these nucleic acids are also included herein.

28 Claims, 59 Drawing Sheets

Exhibit 2

Patent No.:	7,501,118 B2
Application Serial No.:	10/670,184
Applicant(s):	Keith, et al.
Group Art Unit:	1647
Filed:	September 24, 2003
Examiner:	Saoud, Christine J.
For:	HUMAN GENE RELATING TO RESPIRATORY DISEASES AND OBESITY

10/670,184	NOVEL HUMAN GENE RELATING TO RESPIRATORY DISEASES AND OBESITY	05-06-2009::11:39:52
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/670,184

Filing or 371(c) Date:	09-24-2003	USPTO Delay (PTO) Delay (days):	898
Issue Date of Patent:	03-10-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	215
Post-Issue Petitions (days):	+0	Total PTA (days):	683
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
02-18-2009	PTA 36 Months	378	
03-10-2009	Patent Issue Date Used in PTA Calculation		
02-05-2009	Dispatch to FDC	⌘	
01-26-2009	Application Is Considered Ready for Issue	⌘	
01-23-2009	Issue Fee Payment Verified	⌘	
01-23-2009	Issue Fee Payment Received	⌘	
11-13-2008	Sequence Forwarded to Pubs on Tape	⌘	
10-24-2008	Mail Notice of Allowance	⌘	
10-21-2008	Notice of Allowance Data Verification Completed	⌘	
10-21-2008	Case Docketed to Examiner in GAU	⌘	
10-21-2008	Document Verification	⌘	
09-24-2008	Date Forwarded to Examiner	⌘	
09-22-2008	Amendment after Final Rejection		63
09-22-2008	Request for Extension of Time - Granted	⌘	
04-29-2008	Mail Post Card		⌘
04-21-2008	Email Notification		⌘
04-21-2008	Mail Final Rejection (PTOL - 326)		⌘
04-14-2008	Final Rejection		
08-09-2007	Information Disclosure Statement considered		
02-12-2008	Date Forwarded to Examiner		
12-21-2007	Response to a Letter to Comply with the Sequence Rules		
01-09-2008	CRF Is Good Technically / Entered into Database		
12-01-2007	Electronic Review		
11-30-2007	Email Notification		
11-29-2007	Mail Letter Requiring CRF (Unreadable, Non-Compliant, Not Submitted)		
11-13-2007	CRF Diskette Unreadable / Did Not Comply / Required but Not Submitted		
09-12-2007	CRF Is Flawed Technically / Not Entered into Database		
08-28-2007	Date Forwarded to Examiner		
08-27-2007	Response after Non-Final Action		62
08-27-2007	Request for Extension of Time - Granted		⌘

08-09-2007	Information Disclosure Statement (IDS) Filed	✖
08-09-2007	Information Disclosure Statement (IDS) Filed	✖
07-19-2007	Mail Examiner Interview Summary (PTOL - 413)	✖
03-08-2007	Examiner Interview Summary Record (PTOL - 413)	✖
03-26-2007	Mail Non-Final Rejection	✖
03-19-2007	Non-Final Rejection	
09-24-2003	Information Disclosure Statement considered	
10-12-2004	Information Disclosure Statement considered	
01-16-2007	Date Forwarded to Examiner	
01-04-2007	Response to Election / Restriction Filed	90
01-08-2007	Request for Extension of Time - Granted	✖
07-06-2006	Mail Restriction Requirement	✖
07-03-2006	Requirement for Restriction / Election	
07-01-2006	Case Docketed to Examiner in GAU	
10-12-2004	Reference capture on IDS	
06-27-2006	Date Forwarded to Examiner	
06-27-2006	Response to Election / Restriction Filed	
06-27-2006	Request for Extension of Time - Granted	
04-28-2006	Mail Restriction Requirement	520
04-27-2006	Requirement for Restriction / Election	✖
04-14-2006	Case Docketed to Examiner in GAU	✖
10-12-2004	Information Disclosure Statement (IDS) Filed	✖
10-12-2004	Information Disclosure Statement (IDS) Filed	✖
09-24-2003	Information Disclosure Statement (IDS) Filed	✖
09-24-2003	Information Disclosure Statement (IDS) Filed	✖
09-24-2003	Preliminary Amendment	✖
08-09-2004	Correspondence Address Change	✖
07-12-2004	Case Docketed to Examiner in GAU	✖
07-12-2004	IFW TSS Processing by Tech Center Complete	✖
09-24-2003	Reference capture on IDS	✖
01-13-2004	Application Return from OIPE	✖
01-13-2004	Application Return TO OIPE	✖
01-13-2004	Application Dispatched from OIPE	✖
01-13-2004	Application Is Now Complete	✖
12-05-2003	Cleared by OIPE CSR	✖
11-14-2003	IFW Scan & PACR Auto Security Review	✖
10-15-2003	CRF Is Good Technically / Entered into Database	✖
09-24-2003	CRF Disk Has Been Received by Preexam / Group / PCT	✖
09-24-2003	Initial Exam Team nn	✖

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